OUTPATIENT DIALYSIS SERVICES PAYMENT SYSTEM

*payment***basics**

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The policies discussed in this document were current as of September 15, 2020, and reflect any relevant changes implemented in response to the COVID-19 public health emergency as of that date. This document does not reflect proposed legislation or regulatory actions.

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Individuals with end-stage renal disease (ESRD)—irreversible loss of kidney function—require either dialysis or kidney transplantation to survive. In 1972, the Social Security Act extended all Medicare Part A and Part B benefits to individuals with ESRD who are entitled to receive Social Security benefits. In 2018, there were nearly 395,000 fee-for-service (FFS) Medicare ESRD beneficiaries on dialysis, representing about 1 percent of all FFS Medicare beneficiaries.

Because of the scarcity of kidneys available for transplantation, most patients with ESRD (about 70 percent) receive maintenance dialysis. Medicare spending for outpatient dialysis and injectable drugs administered during dialysis was about $12.7 billion in 2018 and is a predominant share of revenues for dialysis facilities.

Beginning in 1983, Medicare paid dialysis facilities a predetermined rate intended to cover a specific bundle of services provided to patients in a given dialysis treatment. To improve provider efficiency, Medicare began in 2011 to phase in a modernized prospective payment system (PPS) for outpatient dialysis services. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) broadened the payment bundle to include dialysis drugs, laboratory tests, and other ESRD-related items and services that were previously separately billable. MIPPA also required CMS to implement a pay-for-performance program beginning in 2012. Beginning on January 1, 2014, all facilities were paid 100 percent under the modernized payment system. Table 1 summarizes the key features of the dialysis PPS.

Defining the care that Medicare buys

Medicare covers two methods of dialysis—hemodialysis and peritoneal dialysis. In hemodialysis, a patient's blood is cycled through a dialysis machine, which filters out body waste. About 88 percent of all dialysis patients undergo hemodialysis in dialysis facilities. Peritoneal dialysis uses the lining of the peritoneal cavity to filter excess waste products, which are then drained from the abdomen. Patients undergo peritoneal dialysis five to seven times per week in their homes.

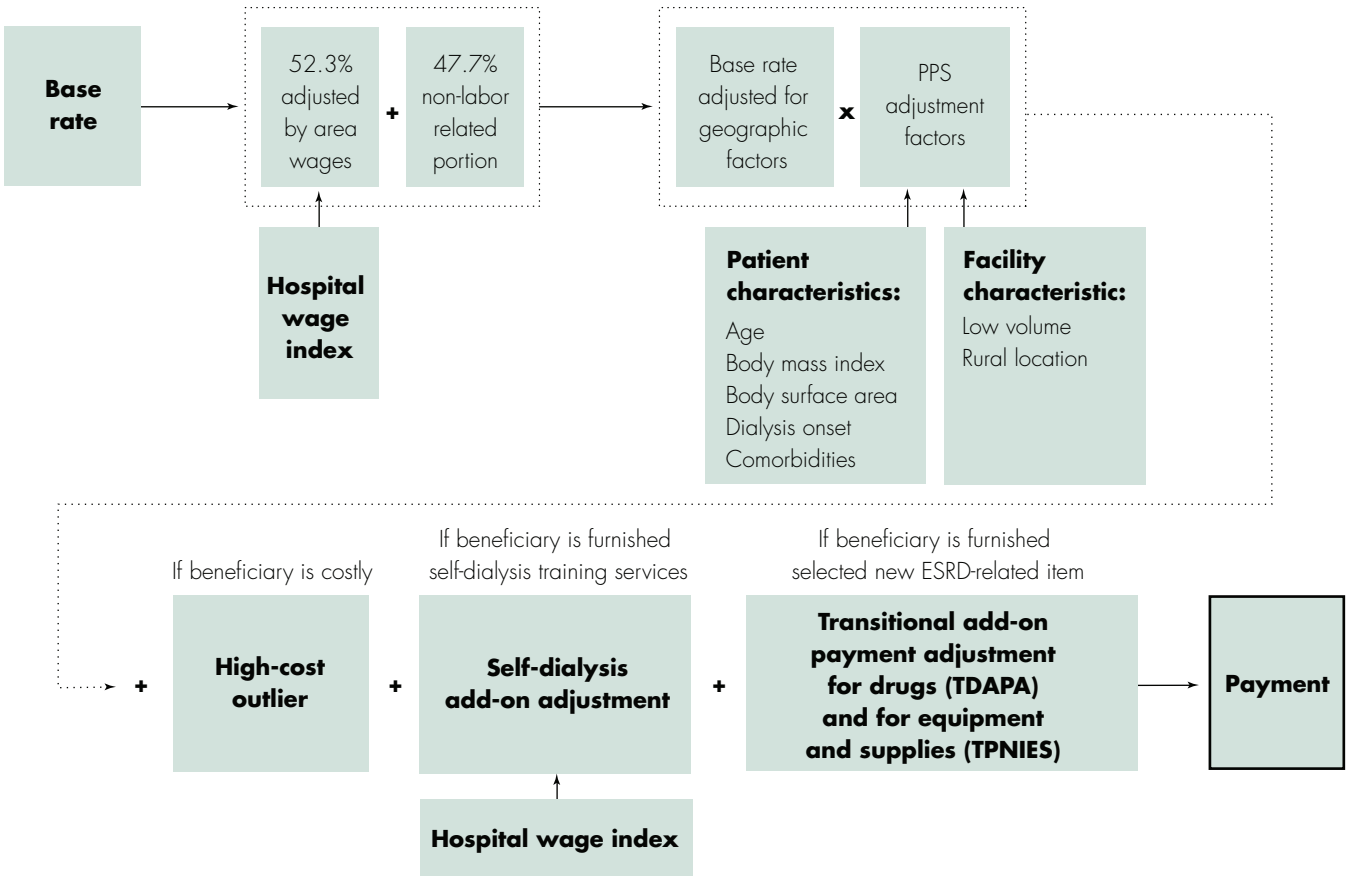
The unit of payment is a single dialysis treatment. Although different equipment, supplies, and labor are needed for hemodialysis and peritoneal dialysis, the payment system that began in 2011 does not differentiate payment based on dialysis method for adults. Medicare's payment rate is based on a regimen of three dialysis treatments per week.

Under the dialysis PPS, facilities are paid a single case-mix-adjusted payment which includes composite rate services and ESRD-related drugs, laboratory services, and medical equipment and supplies. The ESRD drugs included under the broader payment bundle include: (1) Part B ESRD-related drugs (including erythropoietin, injectable iron, and vitamin D analogs), and their oral equivalents; and (2) Part D oral ESRD-related drugs with or without an injectable equivalent (calcimimetics and phosphate binders). Statutory provisions delayed the inclusion of oral-only ESRD-related drugs into the payment bundle until 2025.

Setting the base rate

The base payment for each dialysis treatment is intended to cover all operating and capital costs that efficient providers would incur in furnishing dialysis treatment episodes in dialysis facilities or in patients' homes. For 2020, the base payment rate is $239.33 for freestanding facilities and for hospital-based facilities (Figure 1). The base rate is adjusted for differences in labor costs

Figure 1 Dialysis prospective payment system in 2020



Note: TDAPA (transitional drug add-on payment adjustment), TPNIES (transitional add-on payment adjustment for new and innovative equipment and supplies). This figure represents the dialysis prospective payment system for beneficiaries 18 and older. For beneficiaries under 18: (1) the base rate, adjusted for geographic factors, is multiplied by patient case-mix characteristics (age and dialysis method); (2) the low-volume adjustment and rural factors do not apply; and (3) the outlier payment policy and add-on for self-dialysis training do apply. The payment rate may be reduced by up to 2 percent for facilities that do not achieve or make progress toward specified quality measures.

Source: MedPAC analysis of CMS's final rule for the end-stage renal disease prospective payment system for calendar year 2020.

by multiplying the labor-related portion of the base payment amount (52.3 percent) by a version of the hospital wage index.

Patient-level adjustments—For adults, the wage-adjusted base rate is then adjusted for case mix using the following measures:

- age (18–44, 45–59, 60–69, 70–79, ≥80 years),
- two body measurement variables—body surface area and body mass index,
- specific acute and chronic comorbidities, and
- onset of dialysis (for the first four months a patient receives dialysis).

For children under the age of 18 years, CMS adjusts the base rate by age and dialysis modality.

Facility-level adjustments—CMS makes two facility-level adjustments to the base rate. First, CMS adjusts the base rate by 23.9 percent to account for the costs that low-volume facilities incur. A low-volume facility is defined as one that furnishes fewer than 4,000 treatments in each of the three years before the payment year and that has not opened, closed or received a new provider number due to a change in ownership during the three-year period.

In addition, CMS considers the proximity to other commonly-owned facilities within five miles of the facility in question.

CMS also includes an adjustment (of 0.8 percent applied to the base PPS rate) for all facilities located in rural areas.

Outlier payments

CMS pays facilities an outlier payment when a beneficiary's payment per treatment for outlier services exceeds a threshold, which is the beneficiary's predicted payment amount per treatment for the outlier services plus a fixed dollar loss amount. Outlier services include drugs, laboratory services, and other items that facilities separately billed under the old payment method. Services that are paid under a transitional add-on payment policy are not eligible for outlier payments. The outlier threshold amount for 2020 is $84 for adults. Medicare pays 80 percent of the facilities' costs above the threshold.

Transitional add-on payments for new technologies

In 2016, CMS established a drug designation process (as statutorily mandated) for determining when ESRD-related oral-only drugs—calcimimetics and phosphate binders—are no longer oral only and therefore must be paid under the ESRD PPS. Under the process, once the Food and Drug Administration (FDA) approves an equivalent injectable product (or other non-oral forms), the agency pays facilities for both the oral and non-oral products under a transitional drug add-on payment adjustment (TDAPA) until sufficient claims data (at least two years' worth) for rate-setting analysis are available; thereafter, these drugs (calcimimetics and phosphate binders) will be included in the PPS bundle.

Because an injectable equivalent of the oral calcimimetic was approved by the FDA in 2017, effective January 1, 2018, injectable and oral calcimimetics are the first products to qualify for the TDAPA under the ESRD PPS. In 2020, CMS is continuing to pay for these products under a TDAPA in order to collect sufficient claims data so that a rate setting analysis may be conducted.

In addition to calcimimetics, other qualifying ESRD-related drugs and biologics that the FDA approves on or after January 1, 2020, are eligible for a transitional add-on payment:

* Medicare pays a TDAPA for certain new products (e.g., that are not generics) that treat a condition included in one of 11 ESRD functional categories of products that are covered under the PPS. After the two-year TDAPA period ends, CMS includes the drug in the PPS bundle, without any change to the ESRD PPS base rate.
* Medicare pays a TDAPA for new ESRD products that treat a condition for which there is no ESRD-related functional category for at least two years. Once sufficient claims-based utilization data are available, CMS includes the drug in the PPS bundle, and the base rate is modified, as appropriate, to account for the new product in the bundle.

Under the TDAPA policy, Medicare pays facilities 100 percent of each product's Part B ASP.

In addition, as of 2020, there is an add-on payment—the "transitional add-on payment adjustment for new and innovative equipment and supplies" (TPNIES)—for ESRD-related equipment and supplies that meet certain criteria, including newness and substantial clinical improvement. Equipment and supplies that are considered a capital asset are not eligible for TPNIES. For a two-year period, Medicare pays 65 percent of a qualifying technology's cost using information from invoices and other relevant sources. Thereafter, the piece of equipment or supply is included in the PPS payment bundle, without any change to the ESRD PPS base rate.

Table 1 Key features of the prospective dialysis payment system

Payment method feature	
Payment bundle	• Composite rate services • Separately billable (Part B) injectable dialysis drugs and their oral equivalents • ESRD-related laboratory tests • Selected ESRD Part D drugs • Self-dialysis training services
Unit of payment	Single dialysis treatment
Self-dialysis training services adjustment	Yes
Beneficiary-level adjustments	• For adults: age, dialysis onset, body surface, body mass, specific acute (pericarditis; gastrointestinal tract bleeding or hemorrhage) and chronic (hereditary hemolytic or sickle cell anemias; myelodysplastic syndrome) patient comorbidities • For pediatric patients: age, dialysis method
Facility-level adjustments	• Wage index • Low-volume adjustment • Adjustment for rural location
Outlier policy	Applies to the portion of the broader payment bundle composed of the drugs and services that were previously separately billable
Transitional add-on payment adjustments for selected new ESRD-related items	Pays facilities an add-on payment for the following qualifying ESRD items: (1) drugs and biologics and (2) equipment and supplies.
Quality incentive program	For 2020, 9 outcome measures and 7 process measures.

Note: ESRD (end-stage renal disease), FDA (Food and Drug Administration). Payments for pediatric patients are not eligible for the low-volume or rural adjustments.

Source: MedPAC analysis of CMS 2020 final ESRD rule.

Self-dialysis training add-on payment

In 2020, the dialysis training add-on payment is $95.60 per treatment. CMS pays up to 15 training sessions for peritoneal dialysis and 25 sessions for hemodialysis.

Payment updates

Medicare payments to dialysis facilities are updated annually by the ESRD market basket, which measures the price increases of goods and services facilities buy to produce patient care, reduced by a productivity adjustment.

Quality incentive payment program

The dialysis PPS also includes a quality incentive payment program. Beginning in 2012, the bundled payment rate is reduced by up to 2 percent for facilities that do not achieve or make progress toward specified quality measures. Facility-level scores are publicly reported on-line and posted within dialysis facilities. For the 2020 payment year, the ESRD quality incentive program includes the following measures:

- Dialysis adequacy (i.e., the extent to which dialysis is removing enough wastes and fluid from the body) comprehensive measure for hemodialysis and peritoneal dialysis patients;
- Two outcome measures that assess hemodialysis vascular access—use of autogenous AV fistulas and catheters;
- An outcome measure that assesses the ratio of the number of observed unplanned 30-day hospital readmissions

to the number of expected unplanned 30-day hospital readmissions;
- An outcome measure that assesses the ratio of observed red blood cell transfusions to the number of expected transfusions;
- An outcome measure, the National Healthcare Safety Network bloodstream infection measure, that assesses the number of hemodialysis outpatients with positive blood cultures per 100 hemodialysis patient-months;
- An outcome measure that assesses the proportion of patients with hypercalcemia, an indicator of the management of bone mineral metabolism and disease;
- An outcome measure that uses the in-center hemodialysis Consumer Assessment of Healthcare Providers and Systems Survey instrument to measure, from the perspective of in-center hemodialysis patients, the quality of dialysis care they receive from their nephrologist and from the staff of the dialysis facility;
- An outcome measure that calculates the risk-adjusted standardized hospitalization ratio of the number of observed hospitalizations to the number of expected hospitalizations;
- A process measure that assesses the percentage of patients with documentation of a pain assessment using a standardized tool, and documentation of follow-up when pain is present;
- A process measure that assesses the percentage of patients screened for clinical depression using a standardized tool and documentation of a follow-up plan when necessary;
- A process measure that assesses the percentage of a facility's health care personnel who received an influenza vaccination, had a medical contraindication to vaccination, declined vaccination, or were of an unknown vaccination status;
- A process measure that assesses the number of months for which facilities report the dosage of erythropoietin stimulating agents (as applicable) and hemoglobin/hematocrit of dialysis beneficiaries;
- A process measure that assesses the number of months for which facilities report patients' serum phosphorus levels (an indicator of bone mineral metabolism and disease);
- A process measure that assesses the number of months for which facilities report National Healthcare Safety Network dialysis event data to the Centers for Disease Control and Prevention; and
- A process measure that assesses the number of months for which facilities report all required data elements associated with the ultrafiltration rate for hemodialysis patients. ■